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THE CONCEPT AND DEVELOPMENT OF A LASER AND COSMETIC CARE CENTER

Mary Flor, RN
The Laser and Cosmetic Care Center, Edina MN of Abbott Northwestern Hospital
Minneapolis, Minnesota

OBJECTIVES

The participant will understand the need for the development of a laser and cosmetic care center.
The participant will be able to identify the team members in the development of a new center.
The participant will review Mission and Value statements that direct the development of policy and procedures, staff selection and training, implementation and evaluation of value enhanced services.
The participant will be told how a large non-profit metropolitan hospital developed an off-campus Laser and Cosmetic Care Center in a well-known demographic suburb.

I. The Concept is Developed
II. Who makes up the developing Team
III. The Mission and Values
IV. Policy and Procedures/Credentialing Standards
V. Staff selection and development
VI. Implementing services that provide and enhance alternative treatments available at one Center
VII. Integrating Value-Enhanced Services to promote patient comfort and decrease pre-treatment anxiety, and provide post-treatment services and education with ongoing and continuity of skin care.
VIII. Maintaining a Center for Excellence in research of new technology, quality patient care and ultimate patient satisfaction
IX. Demographic Location

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THE INCREASING NURSING ROLE IN THE USE OF INTENSE PULSED LIGHT SOURCES FOR CUTANEOUS LESIONS

TD Foster, MW Bell, MH Gold
Gold Skin Care Center, Nashville, TN

The intense pulsed light sources for treatment of cutaneous lesions have broadened the scope of therapeutic options available for our clinics to treat the variety of clinical lesions being seen. The intense pulsed light source is an instrument which is utilized by nurses in many states, and it is essential that they have proper training and knowledge of the machines. The nurses will be asked to perform the initial assessment, to perform the full treatment, and to perform follow-up evaluations and treatments when necessary. The nurses, therefore, must assume new responsibilities, which include knowledge of the physics of laser and laser light systems, to adjust parameters on the intense pulsed light sources. One of the major keys to the intense pulsed light success results from having flexible light parameters, including the spectrum of light delivered, the pulse timing and delay, and power supplied. These variables allow both vascular and pigmented lesions to be successfully treated and nurses are taking a major role in this field of cutaneous surgery.

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THREE YEAR EXPERIENCE DEVELOPING A GANG/CULT LASER TATTOO REMOVAL PROGRAM FOR YOUTH

M. Grimm, M. Herbst, P. Plumb, Abbott Northwestern Hospital, Allina Health System, Minneapolis, Minnesota

This study presents results of a three year effort to provide hospital and clinic-based laser tattoo removal and health screening in partnership with community law enforcement and youth-serving organizations. The TRY Program (Tattoo Removal for Youth) was established in 1996 to assist youth make a positive change in their life through the removal of gang/cult-related tattoos and participation in a self-development program with community agencies. This report specifically addresses the unique patient care challenges of the ex gang/cult member, reviews operational and financial support needs, and proposes guidelines for health care institutions, nursing and allied health professionals considering establishing a community tattoo removal program.

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EVALUATION OF THE GEL LIMITING LIGHTGUIDE WITH COOLING (GLLC)

Brian Zelickson,MD Mona Selim, MD Mary Flor, RN Teresa Johnson, RN The Laser and Cosmetic Care Center, Edina MN of Abbott Northwestern Hospital, Minneapolis, MN

The purpose of this study is to evaluate the effects on pain control, side effects and efficacy of using the GLLC during hair removal treatment. Twenty adult subjects were screened by medical history, physical exam, and if needed, laboratory studies to rule out any medical reasons for excess hair. Fitzpatrick skin type, color and coarseness of hair were noted. The patients were off all iron therapy, photosensitive drugs and avoided ultraviolet exposure for two weeks prior to treatment, and for the duration of the study. The subjects were excluded if they were pregnant or lactating. Treatment: Two similar sites were selected, identified, and labeled. They were treated as follows: 1) Pre-determined parameters per protocol for hair removal without the GLLC 2) Pre-determined parameters for hair removal with the exception of increasing the fluence by 5 – 20% based upon clinical endpoint of perifollicular erythema. The subjects were treated 1 –2 times at 4 – 6 week intervals. Post treatment photos were taken to compare immediate response of the treatments. Clinical Assessment: Immediately after each treatment the subjects were asked to evaluate the discomfort level experienced on a scale of 1-10, with 10 being the worst pain they have ever experienced. Prior to each treatment and at 4 to 6 weeks after the last treatment, the treated areas were evaluated for hair counts and side effects. Results: The average value for pain was 5 without the GLLC and 1. 3 with the GLLC. 17 subjects returned for follow-up examinations. The average reduction in hair counts was 34% and 38% for the area with and without the GLLC respectively. Two subjects developed blistering at the site not treated with the GLLC and one of these developed a hypertrophic scar. Conclusions: The GLLC was effective in reducing subjective pain and side effects without effecting efficacy.

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REVIEW OF ADVERSE REACTIONS ASSOCIATED WITH INTENSE PULSED LIGHT

SL Street, TD Foster, MW Bell, MH Gold
Gold Skin Care Center, Nashville, IN

The intense pulsed light source for long-term epilation is a proven modality which yields good clinical results with very few adverse reactions. A review of the potential adverse reactions and management ideas will be presented in this forum. Clinical examples of what may be expected will be shown throughout this lecture. A retrospective analysis of our clinic's experience will be reviewed.

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Discussion of Epidermal Effects Following VascuLight Treatment for Large Vasculature

Michelle Recourt, Kathy Rada
Needham, Massachusetts

Near infrared wavelengths have been utilized for the treatment of large vessel disorder with some success, but often with adverse epidermal side effects. The typical pulse characteristics of these lasers often result in atrophic scarring. The VascuLight™ Intense Pulsed Laser Light system is an FDA approved laser designed for treatment of larger, deeper resistant vasculature. The system operates on the basis of selective photothermolysis, utilizing the optimal light penetration and blood absorption ratio in the near infrared range. The VascuLight™ laser is capable of delivering multiple synchronized pulses which, coupled with the near infrared wavelength, further reduce the events of adverse epidermal responses. The purpose of this study is to report the temperature distribution of the near infrared wavelength in the epidermis, and the associated side effects. A thermal model of the skin was developed to test the distribution of various skin types. A discussion of human histological effects will be reported. Epidermal side effects are minimal despite high energies used to effectively treat large, deep vessels.

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APPROACHING LIGHT SPEED – GROWTH OF LOW LEVEL LASER THERAPY

Carolyn Wafle-Guenther
El Camino Surgery Center
Mountain View, CA USA

The history of the use of laser in medicine is rather brief-spanning about forty years. However, the use of light in medicine has a much more longer history.

A new subspecialty in the medical application of the laser has been developed in the past decade. Low-reactive level laser therapy (LLLT) is one of the fastest growing areas, as well as, one of the most exciting forms of therapy in recent years.

LLLT causes photoactivation which describes a tissue effect where there is no photodestructive change or reaction in the laser irradiated tissue. The laser systems used are Diodes in the 840 or 904 nm. range.

As yet, no LLLT system has been approved by the Food and Drug Administration (FDA) for use is the United States. The FDA has begun their own wound healing studies. This is a major breakthrough!!!

There has been much skepticism regarding LLLT. Some of this skepticism stems from extravagant claims. However, the major hindrance to this form of therapy is the lack of complete or substantiated research data.

LLLT is an accepted treatment therapy and is used routinely in the medical care in many countries. It is known to have widespread acceptance in Australia, Canada, European, and Asian countries. It is widely used in dermatology, wound healing, bone healing, plastic and reconstructive surgery, physiotherapy and rheumatology.

Experimental work continues to further explain the mechanism by which this therapy works. This work includes cellular and photobiology studies, nerve regeneration and tendon healing.

Education, training, and teamwork are necessary elements for a LLLT program. Certainly, a thorough understanding of all aspects of lasers will be a vital element in the advancement of LLLT.

In adequately training hands, the potential for LLLT to improve healthcare is in the infantile stage. It will become the treatment of choice in many specialties. Much remains to be learned about this exciting therapy.

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LOW LEVEL LASER THERAPY: NEW FRONTIERS FOR PERIOPERATIVE NURSES

Penny J. Smalley, Technology Concepts International
Chicago, Illinois, USA

Perioperative nurses have been focused on the care of patients undergoing surgical and dermatologic laser procedures for more than two decades. Lasers changed the practice of nursing and continue to do so with each new wavelength and application. Today, low level lasers are once again challenging nurses to redefine practice, learn new scientific concepts, and devise new and untried methods of patient management appropriate to the therapy. Low level lasers offer non-invasive treatment options for pain relief, reduction of soft tissue swelling, and a number of other indications, in an out patient setting. Not yet FDA approved, and limited to clinical trials, LLLT has been the subject of debate for years, often disregarded as a fringe type of treatment. Today, it has the attention of the mainstream, with increasing acceptance of non-traditional, complimentary, and alternative medicine. This is evidenced by the growing number of articles in peer reviewed journals, papers being presented at conferences, companies sponsoring trials, and the establishment of the North American division of the World Association of Laser Therapy. LLLT has been limited to the practice of physiotherapists, dentists, and veterinarians, but is an application ideally suited for nursing involvement, requiring knowledge of physical assessment, care planning, patient education, and patient management. LLLT offers a true multidisciplinary approach to treatment, and a new and exciting opportunity for nurses.

OPTICAL DIAGNOSTICS

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Laser Induced Fluorescence Diagnosis in the Oral Cavity
TS Mang[1], J Kost[2], V Yang, BC Wilson[2]
State University of New York at Buffalo[1], Ontario Cancer Institute Princess Margaret Hospital[2]

Much interest has been shown in fluorescence imaging, particularly in the lung, GI tract and cervix. An imaging device was constructed using excitation wavelengths and emission windows shown to discern dysplasia/carcinoma from surrounding normal mucosa.

The device was tested in the hamster cheek pouch DMBA model of transforming mucosa. This allows for imaging of squamous cell carcinoma at differing stages of disease progression. Corresponding histopathology was used to confirm the presence of disease and corresponding stage.

Results from these studies demonstrate good correlation between the spectroscopic findings corresponding to malignant transformation and sensitivity of detection over standard observation. Imaging using prototype devices has been significantly enhanced through the use of exogenous photosensitizing agents.

The routine examination of asymptomatic as well as symptomatic patients could lead to detection of early stage cancers. Imaging may eventually be utilized to detect malignant transformation leading to earlier intervention and more successful cure rates.

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Tissue Autofluorescence: an Aid for Glioma Resection Margin Delineation during Surgical Operation.

G.Bottiroli, A.C. Croce, D. Locatelli, R. Nano, K.S. Lanza, E.Giombelli*, F. Tancioni*, E. Benericetti*
*Centro Studio Istochimica CNR, Pavia; *Reparto Neurochirurgia , Az. Ospedaliera "E. Morelli" Sondalo; Italy.*

Most gliomas do not exhibit a boundary easily distinguishable from normal surrounding tissue on the basis of their gross anatomy; this makes a complete resection difficult or impossible to obtain in surgical operation. The result can be either incomplete resection of the tumor mass, the main cause of early recurrence of the disease, or excessive resection of the healthy tissue, causing additional neurological deficits. In this work, the potential of light-induced fluorescence spectroscopy to delineate tumor margins was studied. Spectrofluorometric analysis was performed on tissue sections from surgical resections, and in vivo during surgical operation on patients affected by glioma with different degrees of malignancy. Scan-microspectrofluorometric analysis performed in the 420–640 nm range, under excitation at 366 nm, along tissue sections, evidenced both a reduction of the emission amplitude and a modification of the spectral shape from peritumoral non-neoplastic to neoplastic tissues. Measurements performed on patients in vivo, by means of a fiber optic probe, under the same excitation conditions, indicated that both low- and high- grade gliomas are characterized by i) a significant reduction in the emission amplitude (more than 60%), ii) an increase of the 520-540/460-480 nm fluorescence intensity ratio, indicating a broadening of the emission spectrum, and iii) a shift of the peak position (about 10 nm) towards longer wavelengths, with respect to cortex and white matter, considered as normal tissues. The results open interesting prospects of improving the efficacy of neurosurgical operations through a real-time diagnostic technique for delineation of brain tumor resection margins.

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THE EFFECT OF SUPERPULSED CO_2 LASER ON KELOID AND NORMAL DERMAL FIBROBLAST SECRETION OF GROWTH FACTORS: A SERUM-FREE STUDY

Kenneth C. Nowak R. James Koch
Stanford University Medical Center

Purpose: An *in vitro* model was used to determine the effect of superpulsed CO_2 laser (SCO_2) on normal dermal and keloid-producing fibroblasts. Basic fibroblast growth factor (bFGF) is mitogenic and inhibits collagen production. Transforming growth factor-beta 1 (TGF-ß1) stimulates growth and collagen secretion and is thought integral to keloid formation. Growth in serum-free media was used to assay these growth factors.

Methods: Keloid and normal dermal fibroblast lines were established using standard explant techniques. Cells were used at passage four to seed 24-well trays at a concentration of $6x10^4$ cells/ml in serum-free media (Ultraculture, Biowhitaker). At 48 hours, 18.8% of each cell well was exposed to a fluence of 4, 6, or 8 J/cm^2 using SCO_2. Control wells received no SCO_2. Cell viability and counts were established at time = 0 (time of SCO_2 treatment), 24, 72, and 120 hours. Supernatants were collected and assessed for bFGF and TGF-ß1 using a sandwich enzyme immunoassay.

Results: All cell lines demonstrated growth after 48 hours from time = 0 hours (laser irradiation) to time = 120 hours (experiment conclusion) with a slightly shorter doubling time for keloid fibroblasts. SCO_2 shortened doubling times to an average of 85.7 hours (4 J/cm^2) compared to 124.8 hours (control). Decreased viability was seen with increasing fluence (mean survival = 91.3%). TGF-ß1 levels increased over time in 83%, however this rate of increase was suppressed in both keloid and normal fibroblasts by SCO_2 (most significantly at 6 J/cm^2). bFGF decreased over time in 92%. A greater decrease was seen in laser treated and keloid cells.

Conclusions: Serum-free culture sustains cell proliferation and allows for measurement of growth factors without background contamination from serum-containing media. SCO_2 may be effective in enhancing wound healing through increased fibroblast replication. Secretion of TGF-ß1, a precursor to keloid formation, appears to be suppressed by SCO_2. bFGF decays over time and is more pronounced in keloid fibroblasts. The use of SCO_2 to excise keloids may be supported by the selective decrease in TGF-ß1 suggested by this study.

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PHOTON RECYCLING: A NEW METHOD OF ENHANCING HAIR REMOVAL

R. Rox Anderson [1], Christine Dierickx[1], Gregory B. Altshuler[2], Henry H. Zenzie[2]
[1]Massachusetts General Hospital
[2]Palomar Medical Products, Inc.

It is well-known that a significant portion of visible light incident on the skin is reflected and scattered in the reverse direction. Most of this light arises from multiple scattering

in the skin. The reflection coefficient depends on the ratio of the average scattering factor to the average absorption coefficient. This ratio reaches a maximum in the red/near IR portion of the spectrum and will be higher for light skin (low absorption) than dark skin (high absorption). By incorporating elements in the laser handpiece that reflect scattered light back to the skin (photon recycling), the radiance in the skin can be significantly increased. Theoretically, for light skin in the red spectral region, photon recycling can increase the radiance by a factor of 2-5. In an in-vitro study with a ruby laser, this effect was shown to produce a 50% higher temperature increase in an absorbing target placed inside animal skin. Photon recycling was incorporated into the handpiece of a ruby laser for hair removal (Palomar E2000). In an in-vivo study, a gain in efficacy for hair removal was observed with photon recycling.

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DETERMINATION OF BURN DEPTH BY POLARIZATION SENSITIVE OPTICAL COHERENCE TOMOGRAPHY

Shyam M. Srinivas, Johannes F. de Boer, B. Hyle Park, Kourosh Keikhanzadeh, Huai-en L. Huang, Zhongping Chen, J. Stuart Nelson
Beckman Laser Institute and Medical Clinic
University of California, Irvine

Burn depth assessment is a key step in guiding the treatment plan in patients who have sustained burn injuries. Currently this is done by visual inspection of the burn to estimate the degree of injury. We have developed a technique, Polarization Sensitive Optical Coherence Tomography (PS-OCT) to image the burns, designed to ultimately give physicians a quantitative estimate of the actual burn depth. The technique allows for imaging birefringence in biological tissue, through the change of the polarization state of light reflected from the sample. The decrease of collagen birefringence in skin due to denaturation by thermal damage allows determination of burn injury. We generated burns of various depth by contacting rats with a brass rod preheated to 75°C for 5, 15, and 30 sec. A reduction of birefringence was measured by the PS-OCT device up to a depth of approximately 0.18, 0.27, and 0.38 mm, respectively. The correlation has been evaluated between birefringence reduction and actual burn depth by biopsy and corresponding histological analysis of the burned rat skin. Preliminary results show that PS-OCT is a noninvasive technique which potentially can give physicians the accuracy to formulate the best treatment plan for their burn patients.

ORTHOPEDIC SURGERY

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HISTOLOGIC, SEM, AND FTIR EVALUATION OF IN-VIVO CORTICAL BONE ABLATIONS USING AN FEL AT 3.0, 6.1 AND 6.45 μm.

George M. Peavy[1], Charles M. Cobb[2], Paulette Spencer[2], John T. Payne[3], Lou Reinisch[4] and John M. Kreeger[5]
[1]Beckman Laser Institute and Medical Clinic, University of California, Irvine, [2]University of Missouri-Kansas City, [3]Cincinnati, Ohio, [4]Vanderbilt University, and [5]Universtiy of Missouri-Columbia

Purpose: To evaluate in-vivo cortical bone ablations made using wavelengths and a pulse duration based on IR bone absorption and ex-vivo ablation characteristics. Methods: The tibias of 12 anesthetized rabbits were exposed medially. One circular and 3 linear cortical ablations were made using an FEL tuned to 3.0, 6.1 and 6.45 μm wavelengths and a 4.0 μsecond macropulse at 30 Hz. Laser beam was directed by a computer controlled delivery system. Pulse energy was 22.5 ± 2.5 mJ/pulse, delivered in one complete pass over the ablation area in either a 200 μm (71.7 J/cm^2) or 500 μm (11.5 J/cm^2) spot. Total fluence for each ablation was either 660 J/cm^2 (200 μm spot) or 230 J/cm^2 (500 μm spot). Rabbits were euthanized following the ablations, and tibia specimens submitted for histology, SEM and FTIR analysis. Results: Histology revealed clean ablations with collateral thermal injury of 4.5 - 7.5 μm at 230 J/cm^2 and 9.0 - 12.0 μm at 660 J/cm^2 for each wavelength. Depth of ablation was greater for ablations made using wavelengths 6.1 and 6.45 μm than for the 3.0 μm. SEM evaluation revealed a uniform surface of collagen tufts of varying degrees of melting, occasional intact calcium hydroxyapatite crystals protruding from or resting on the surface, and no evidence of micro fissures. FTIR photoacoustic analysis revealed minimal spectral differences in the ablated and non-ablated surfaces, with a small decrease in the relative intensity of the Amide III at the ablated sites. This is consistent with minimal changes in the collagen of cortical bone at the ablation surface. Conclusions: Cortical bone ablations can be made in-vivo with minimal collateral thermal injury or chemical alteration using wavelengths 3.0, 6.1, and 6.45 μm and a pulse duration of 4.0 μsecond. Ablation efficiency is much greater with the 6.1 and 6.45 μm than with the 3.0 μm wavelength.
This work was made possible by grant numbers N00014-94-1-1023 and N00014-94-0874 from the Office of Naval Research.

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COMPARISION OF BONE HEALING FOLLOWING CORTICAL OSTEOTOMY USING A BONE SAW AND A 6.1 μm, 4.0 μSECOND FREE ELECTRON LASER

John T. Payne[1], George M. Peavy[2], Lou Reinisch[3], David C. Van Sickle[4] and John M. Kreeger[5]
[1]Cincinnati, Ohio, [2]Beckman Laser Institute and Medical Clinic, University of California, Irvine, [3]Vanderbilt University, [4]Purdue University, and [5]Universtiy of Missouri-Columbia

Purpose: To compare healing of cortical bone following osteotomy using a pneumatic bone saw to a laser osteotomy using 6.1 μm wavelength and 4.0 μsecond macropulse structure of an FEL. Methods: The tibias of 16 rabbits under general anesthesia were exposed and controlled cortical incisions were made using either a pneumatic bone saw or an FEL tuned to 6.1 μm wavelength and a 4.0 μsecond macropulse at 30 Hz. One proximal and 1 distal incision were made on the medial aspect of each tibia of each rabbit. An equal number of both partial and full cortical thickness bone saw and laser incisions were made, and site selection for each was randomly selected. Pulse energy was 22.5 ± 2.5 mJ/pulse, directed into a 200 μm spot (71.7 J/cm^2), and delivered in passes across the ablation line by a computer controlled delivery system for uniform surface exposure. Rabbits were survived for 2, 4, 6 and 8 weeks post surgery, euthanized at the designated time point, and the incision sites were evaluated grossly and by histologic evaluation. Results: Evaluation of the healing of the osteotomy sites revealed rapid and complete healing of the laser osteotomy sites, which was judged to be as good or better than the bone saw osteotomy sites. Conclusions: Cortical bone incisions made using a laser at 6.1 μm wavelength and a pulse duration of 4.0 μsecond, shows no delayed healing, and is judged to heal as well or better than an osteotomy made using a conventional bone saw.
This work was made possible by grant numbers N00014-94-1-1023 and N00014-94-0874 from the Office of Naval Research.

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Treatment of eccrine syringofibroadenoma with a flashlamp pumped pulsed dye laser. M. Trauner MD, B. Ruben MD and Vic Narurkar MD. UC Davis Laser Center and Bay Area Laser Institute, Sacramento, CA and San Francisco, CA

We report the treatment of an unusual presentation of eccrine syringofibroadenoma, a rare dermal adnexal tumor with a dual pulse width flashlamp pumped pulsed dye laser. The neoplasm presented as a chronic non-healing ulcerated plaque on the great toe resulting after multiple orthopedic procedures. Conventional destructive modalities were unsuccessful and surgery was not an option due to exacerbation of the ulcer.

Treatment was performed with a 585nm and 595nm pulsed dye laser every two weeks for a total of nine treatments, resulting in complete resolution of the ulceration and substantial clearance of the neoplasm.

Eccrine syringofibroadenoma is a rare adnexal neoplasm with a rich fibrovascular stroma. The rationale for the use of a pulsed dye laser was the presence of heavily vascularized target and non-specific destruction at high fluences. A review of the literature of this neoplasm did not produce specific treatment approaches.

We conclude the flashlamp pumped pulsed dye laser provided a safe, effective and minimally invasive method for the treatment of a resistant dermal adnexal neoplasm

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CERVICOGENIC HEADACHES SECONDARY TO C5/C6 – C6/C7 CERVICAL DISC DISEASE, RELIEVED BY ENDOSCOPIC LASER CERVICAL DISCECTOMY – A PRELIMINARY REPORT OF 25 CASES.

Michael Perry, Chet Janecki, Alfred Bonati, David Hirschauer, Fred Turner, Anthony Mork, Leonel Perez-Limonte, The Bonati Institute, Hudson, Florida

Cervicogenic headaches have traditionally been thought to be due to pathology of the C2/C3 level or the greater occipital nerve. The purpose of this study is to determine if cervicogenic headaches can be caused by C5/C6 –C6/C7 cervical disc pathology and if they will be relieved by endoscopic laser cervical discectomy directed at those levels.

Twenty-five female patients were studied. The average age was 44 (range 29-50). All patients had cervical disc pathology at the C5/C6 and/or C6/C7, as verified by MRI. All patients had headaches that met Sjastaad Criteria for cerviogenic headaches and were further characterized by the International Headache Association Assessment Protocol. All patients had prior treatment without success. All patients underwent endoscopic laser discectomy.

The 25 patients in this study underwent 45 endoscopic laser discectomies at the C5/C6 and/or C6/C7 levels. Visual analog scale demonstrated that 24 of the 25 patients characterized their preoperative pain as 10 of 10. Postoperatively 23 patients characterized their pain as 0 of 10: one patient did not improve. Average follow-up was 13 months (range 5months-22months).

Cerviogenic headaches can occur as a result of C5/C6-C6/C7 cervical disc pathology. The mechanism is still unclear. Endoscopic laser discectomy is an excellent treatment modality not only for cervical disc disease but also for associated cervicogenic headaches.

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THERMAL, MECHANICAL, OPTICAL AND MORPHOLOGICAL CHANGES IN BOVINE NUCLEUS PULPOSUS INDUCED BY ND:YAG LASER-MEDIATED HEATING

Joon Y Choi [a], Brian JF Wong [bc], B Samuel Tanenbaum [d], Thomas E Milner [e], Emil N Sobol [f], J Stuart Nelson [b], Xavier V Dao [g]
[a] *University of Rochester School of Medicine and Dentistry, NY*
[b] *Beckman Laser Institute, University of California, Irvine*
[c] *Department of Otolaryngology/Head and Neck Surgery, University of California, Irvine*
[d] *Department of Engineering, Harvey Mudd College, CA*
[e] *Biomedical Engineering Program, The University of Texas at Austin*
[f] *Center for Technological Lasers, Russian Academy of Sciences, Troitsk, Moscow Region, Russia*
[g] *University of California, Irvine*

In order to examine the effect of laser irradiation on herniated discs during surgical procedures such as Percutaneous Laser Disc Decompression (PLDD), bovine nucleus pulposus specimens were irradiated using the Nd:YAG laser (λ=1.32 μm) at varying irradiances between 9W/cm^2 and 31W/cm^2. During laser irradiation, the thermal, mechanical, optical and morphological changes of the specimen were monitored by recording, respectively, radiometric surface temperature, internal tension, integrated backscattered light intensity (from a probe HeNe laser, λ=632.8nm) and endoscopic images. In addition, the irradiated tissue specimens were compared with the air-dried controls after immersion in saline for two days. The mass reduction following irradiation was measured at different irradiances. Results indicate that a peak in integrated backscattered light intensity occurs when radiometric surface temperature reaches approximately 65 to 75 °C. Internal tension increases, peaks (at 1-20% from the baseline), and then decreases during irradiation; a net increase in tension of up to 10% is observed after irradiation suggesting a reduction of specimen length and volume. At higher incident irradiance, the rate of change in the time-dependent internal tension increases as does the steady-state surface temperature. Vaporization and specimen volume reduction are observed during frame-by-frame analysis of video images recorded during irradiation; at high power densities, formation of vapor bubbles within the nucleus tissues is observed. Irradiated tissues do not return to their original shape following two days of saline immersion in contrast to air-dried samples (which return to their original shape and size). Mass reduction following irradiation also increases (19% to 72%) with increasing irradiance. Results of this study suggest that laser mediated heating can achieve effective and irreversible volume reduction in nucleus pulposus of the intervertebral disc.

OTOLARYNGOLOGY/ PULMONARY

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NASAL POLYPOSIS: INTERSTITIAL LASER DESTRUCTION

M. Plouzhnikov, I.P. Pavlov Medical University, St. Petersburg, Russia

An attempt was made to clinically evaluate the technique of interstitial lasing developed and advocated by R. Chapman (1998). Nd:YAG laser was employed in various clinical forms of nasal polyps at 6-8 W output at the fiberoptic tip plunged into pathologic tissue at the roots of polyps. The duration of thermotherapy was dependent on size and histological structure of polyps and varied from 10 to 20 min. No intraoperative complications were registered. Postoperatively, by the 3rd day, the nasal cavity was free from polyposis with no signs of oedema or bleeding and excellent nasal breathing. Follow-up was too short to evaluate long-term results. The technique is believed to be especially safe and handy when used in polyposis involving the roof of nasal cavity not infrequently causing CSF leakage at traditional surgery.

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LASER-ASSISTED SURGERY OF THE NASAL SEPTUM

Yosef P. Krespi, MD
New York, NY

Nasal surgery to improve airway obstruction is the most common surgical procedure performed in Otolaryngology. A new simple, minimally invasive office technique of septoplasty, under local anesthesia, using a CO2 laser with a scanner is described. This technique has a specific clinical application in chronic nasal obstruction due to moderate anterior septal deviation in adults. It is less invasive than traditional septoplasty and potentially more advantageous in terms of reduced surgical time, decreased patient recovery time, less morbidity, lower medical costs, and rapid return to full activity. Ablation of the septum is performed with a CO2 laser and includes lasing of the nasal mucosa, perichondrium, fibro-connective tissue and part of the septal cartilage. The CO2 laser with scanning device and a nasal tip accessory were used to perform this procedure. It is advised that laser septal surgery is performed below the level of the middle turbinate to avoid perforation and adhesions.

Retrospective review of 150 patients from August 1995 to September 1998 was completed. Patient evaluation pre and post operatively was conducted with anterior rhinoscopy, intranasal endoscopy and acoustic rhinometry. There were no incidences of septal perforation, synechia formation or hemorrhage. Surgical success, defined by improvement of nasal obstruction, was achieved in 95% of patients. Acoustic rhinometry revealed a significant increase in the mean minimal cross-sectional area, and the mean nasal cavity volume and a decrease in the mean nasal airway resistance after treatment. This new technique appears to be a safe, quick, simple, predictable, bloodless and virtually painless in-office procedure with excellent results.

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HOLMIUM:YAG-LASER TREATMENT OF HYPERPLASTIC INFERIOR NASAL TURBINATES

Philip Janda[1], Ronald Sroka[2], Reinhold Baumgartner[2], Gerd Grevers[1], Andreas Leunig[1]
[1]Department of Otorhinolaryngology, Head and Neck Surgery [PJ, GG, AL] and [2]Laser Research Laboratory [RS, RB]
University of Munich, Klinikum Grosshadern, Marchioninistr. 15, 81366 Munich, Germany

Since the original reports of Oswal and Bingham as well as Kautzky on a pilot study about the successful use of Ho:YAG-laser in nasal turbinate surgery, no clinical study has been performed on this procedure. The aim of our clinical study was to assess the long term effect of Ho:YAG-laser in the treatment of hyperplastic inferior nasal turbinates.

57 patients were included in this study, all of them being refractory to conservative medical treatment. A pulsed Ho:YAG-laser (Dornier Medilas H, Germering, Munich, F.R.G.) with a wavelength of λ=2100 nm was used for intranasal treatment.

89% and 86% respectively of the patients had an improvement of nasal airflow ½ and 1 year after laser treatment, which was confirmed by rhinomanometry. In the first two weeks, nasal obstruction was correlated directly to the extent of nasal crusting. Following laser treatment, the mucociliar function test was unchanged.

The principle advantages in Ho:YAG-laser treatment of hyperplastic turbinates are the following: the procedure can be performed as an outpatient surgery under local anesthesia with controlable ablation of soft tissue in a short operation time with satisfactory results. In addition the procedure showed excellent patient acceptance.

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Combined CO2 Laser Septoplasty, Turbinate Resection and LAUP

Joseph P. Mirante, MD, MBA, FACS
Ormond Beach, FL

Michael A. Munier, MD, FACS
Ormond Beach, FL

Laser assisted palatoplasty has gained acceptance as a tool for the treatment of snoring. It has advantages as an outpatient procedure performed under local anesthesia with a reasonable success rate and a low complication rate. Laser septoplasty and laser turbinate resection has been applied successfully to the problem of nasal obstruction, which can exacerbate snoring. In our experience the performance of these procedures in an outpatient setting is an effective combination that is well tolerated in the adult population. By staging the nasal procedure with one side completed with first stage LAUP and the second side completed with second stage LAUP patient comfort is improved and acceptance is excellent. Based on patient responses in a series of 25 patients 88 percent noted improvement in nasal breathing and snoring symptoms. There were no major complications. Minor complications included limited epistaxis only.

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DEVELOPMENT OF A NEW TOOL FOR APPLICATION OF LASERS IN NASAL TURBINATE SURGERY

Peter Rösler[1], Ronald Sroka[1], Andreas Leunig[2], Philip Janda[2]
[1]Laser Research Laboratory [PR, RS] and [2]Department of Otorhinolaryngology, Head and Neck Surgery [AL, PJ]
University of Munich, Klinikum Grosshadern, Marchioninistr. 15, 81366 Munich, Germany

Nowadays chronical obstruction of nasal breathing is increasingly treated with laser supported tissue-ablation and -coagulation. In order to optimize this kind of treatment a new instrument, was developed and tested within the scope of a clinical study with a Holmium:YAG-laser, wavelength λ=2100nm (Dornier, MediLas H, Germering, Munich, F.R.G.)

For easy and accurate handling a flexible fiber (type H-4080-B, diameter 400µm) can be inserted into the tool, which is able to bend the distal fiber-end from -5° up to 50°. Thus the operator has the possibility to work in areas which do not allow easy success. Moreover an additional channel for aspiration is included to remove toxic smoke and to keep the operation area clear. The instrument's similarity to a pair of scissors enables the surgeon to

become accustomed to this form very quickly, allowing exact surgery and minimising the risk of unnecessary movements. The comfortable and precise use of this tool, combined with the ability to do without an assistant (formerly required for aspiration) offers the operator a time-saving and cost-effective alternative.

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LASER INTRADUCTAL PHOTOCOAGULATION OF BILATERAL PAROTID DUCTS FOR REDUCING DROOLONG OF CEREBRAL PALSIED CHILDREN

CHENG-JEN CHANG, ALICE MAY-KUEN WONG, LI-RONG CHEN, MIAO-MING CHEN

Department of Plastic and Reconstructive Surgery, Chang Gung Memorial Hospital Taipei, Taiwan

Purpose: Previous reports suggested that surgical treatment was effective to reduce abnormal, profuse drooling in children with low cognitive function, but with risk of complications. Laser photocoagulation might be an option to simplify the procedure and decrease complications. Our study considered whether laser photocoagulation could improve drooling in children with cerebral palsy (CP).

Methods: CP children with drooling were recruited from the pediatric rehabilitation clinic, all of whom had persistent profuse drooling after 6 months of conservative treatment. They received neodymium: yttrium aluminum garnet (Nd: YAG) laser for intraductal photocoagulation to bilateral parotid ducts, and were followed up for 3 to 24 months. Each patient was assessed before and after the procedure by: 1) questionnaire-based semiquantitative assessment of drooling severity and frequency (Thomas-Stonnell and Greensberg 1988); 2) quantitative assessment of saliva amount by collection of stimulated saliva for 2 minutes in cooperative children.

Results: Twenty-four CP children with severe drooling received laser photocoagulation, twenty of them had remarkable decrease of drooling 1 month later. Patients had cool liquid intake soon after the procedure, and were discharged on the second day after treatment. A period of transient face swelling ranged from 6 to 37 days. No antibiotic treatment was indicated nor were any complications noted after the procedure.

Conclusion: As a result of these studies, it is suggested that laser intraductal photocoagulation of bilateral parotid ducts could be used as a simple and effective procedure for reducing drooling in CP children, and would avoid complications form conventional surgery.

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INVESTIGATIONS TO THE DURATION OF WOUND HEALING FOLLOWING LASER SURGICAL EXCISION OF CARCINOMAS OF THE ORAL CAVITY AND THE OROPHARYNX

Authors: B.M. Lippert, B.J. Folz, Ch. Kuelkens, J.A. Werner
Dept. of Otolaryngology, Head and Neck Surgery, Philipps-University Marburg, Germany

Purpose: This investigation was initiated to determine in which way the duration of wound healing is dependant on the size of the lesion and whether differences between CO_2 laser and Nd:YAG laser wounds are noticable. Methods: A group of 24 patients (16 patients CO_2 /8 patients Nd:YAG) were treated for carcinoma of the oral cavity or the oropharynx by laser surgery. The laser parameters were the following: CO_2 laser: 4076-8152 W/cm^2; Nd:YAG laser: 2359-4718 W/cm^2. The initial defect was measured in two planes and the time interval until total reepithelialization was achieved was noted. Results: The duration of wound healing showed a clear dependance on the size of the initial defect. Differences were also noticable between CO_2 and Nd:YAG laser wounds. The average duration of wound healing after CO_2 laser surgery (32.8±9.2 days) was significantly shorter than after Nd:YAG laser surgery (40.4±9.2 days). This finding was even more significant when defects of about the same sizes were compared. The functional results did not show any differences in both groups. Discussion and Conclusion: The explanation for the delayed wound healing after Nd:YAG laser surgery as compared to CO_2 laser surgery can be seen in the more pronounced zone of necrosis after Nd:YAG laser surgery, which hinders the revascularization of the wound in a higher degree. However this observation does not seem to have a negative influence on functional results.

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TREATMENT OF CARCINOMAS OF THE ORAL CAVITY AND THE OROPHARYNX WITH THE Nd:YAG LASER IN FIBERTOM MODE

Authors: B.J. Folz, B.M. Lippert, I.P. Graeber, J.A. Werner
Dept. of Otolaryngology, Head and Neck Surgery, Philipps-University Marburg, Germany

Purpose of study: The Nd:YAG laser in fibertom mode is a new device for surgical resection. The aim of the study was to investigate the feasibility of the device in surgical oncology and to study the tissue effects as well as wound healing. Method: A group of 40 patients with carcinoma in the oral cavity and oropharynx underwent resection of the tumor with Nd:YAG laser in fibertom mode. This group was compared retrospectively to a group of patients, who had undergone laser resection with the CO_2 laser for carcinoma of similar locations. Data wer raised to duration of the operation, duration of wound healing, complications and first oncologic results. Results: Epithelialization of the resection margins was on an average achieved after 21 days when working with Nd:YAG laser as opposed to 25 days, when working with the CO_2 laser. With the Nd:YAG laser duration of the operation was reduced by 27% when compared to CO_2 laser operations. Postoperative hemorrhages were seen in 4 patients after Nd:YAG fibertom surgery and in 7 patients after CO_2 laser surgery. A minimum clinical follow-up of 2 years shows that the oncologic results are certainly not worse than the results after CO_2 laser surgery or surgery with the electric knife. Conclusion: Nd:YAG laser surgery in fibertom mode seems to be suitable for the resection of oral cavity and oropharyngeal carcinomas and may even be superior to CO_2 laser surgery for these indications.

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The using of optical coherent tomography intrasurgical detection of larynx carcinoma borders.

N.Shakhova, A.Shakhov, A.Terentjeva, N.Gladkova, F.Feldchtein* and V.Kamensky*.
Medical Academy of Nizhny Novgorod, Russia
*Institute of Applied Physics of Russian Academy of Sciences, Uljanov , st. 46, 603600, Nizhny Novgorod, Russia

The optical coherence tomography [OCT] is rapidly progressing method gives a capability to image different biotissues. In our report we present the results of the first clinical studies of using the OCT opportunity in intrasurgical detection of larynx carcinoma borders. We have used a endoscopic OCT device that enables to produce images at the 0.83 μm wavelength with the rate of approximately frame/second for [200*200 pixel] tomogram. The results of OCT have correlated with the morfological date.

We studied 18 patients with carcinoma T_1, T_2 stage of the larynx and carcinoma *in situ*. All patients have been operated surgical YAG:Nd laser with two switchable wavelengths at 1.44 μm and 1.32 μm by laryngofissura, direct laryngomicroscopy and fibrolaringoscopy.
The using of this wavelengths demonstrate better coagulation properties of 1.32 μm in comparing with 1.44 μm, and optimal cutting of last one. The information on structural alterations of larynx mucosa in the depth up to 2 mm, obtained by OCT make it possible to be clearly defined the tumor borders, especially when we have no possibility to confirm the diagnosis with morphology investigation of the tumor borders in postoperative period. Besides, OCT can be used for carrying out a directed biopsy and monitoring the regeneration process after organpreserving operations, as a laser resection or vaporization of larynx carcinoma.

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LASER SURGERY OF THE LARYNX IN THE PAEDIATRIC PATIENT: LASER ASSISTED EPIGLOTTOPEXIE-A NEW METHOD OF WIDENING THE AIRWAYS
Authors: J.A. Werner, B.M. Lippert, B.J. Folz, I.P. Graeber
Dept. of Otolaryngology, Head and Neck Surgery,
Philipps-University Marburg, Germany
Purpose: Upper airway obstruction in paediatric patients can be caused by a multitutde of pathologic changes. Presenting symptoms might vary from mild impairment to severe distress with stridor as the objective finding in dramatic cases. Patients and Methods: The charts of all paediatric patients, who were treated by laser surgery for laryngeal airway obstruction between 1994-1998 were reviewed for the underlying disease, therapy, complications and final results. Results: Most common indication for laser surgery of laryngeal disorders in paediatric patients (17 p.) was juvenile papillomatosis, followed by laryngeal stenosis following long-term intubation (12 p.). Less frequent diagnoses were laryngomalacia (5 p.) and subglottic hemangioma (1 p.). Patients were treated by CO_2 laser surgery in all cases except for the subglottic hemangiomas, who were treated by Nd:YAG laser surgery. For the treatment of laryngomalacia type IV laser assisted epiglottopexie was found to be a very reliable method. An emphasis of this presentation is put on the description of this new laser surgical method. In all cases good results could be achieved by laser surgery with regard to relief of dyspnoea. The voice could be preserved in all patients, however intermittent hoarseness is a common finding. Deglutition was not impaired, even after repeated treatment as it is necessary e.g. in juvenile papillomatosis. Conclusion: Laryngeal airway obstruction of various entities in paediatric patients can be treated very effectively by laser surgery.

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LASER SURGERY FOR LARYNGOMALACIA: PRELIMINARY RESULTS OF ANATOMICALLY BASED TECHNIQUE
Udayan K. Shah, M.D. and Ralph F. Wetmore, M.D.
The Children's Hospital of Philadelphia. Philadelphia, PA

Laryngomalacia is a neuro-muscular weakness of the supraglottic airway that causes airway obstruction in neonates and infants. The disorder usually resolves spontaneously. When the severity of the airway obstruction requires surgery, predictive factors that indicate the need for operative correction may be summarized in a form that we have developed. Our operative technique is based upon the specific anatomic conformation responsible for supraglottic prolapse. We discuss preliminary results over the past 18 months in five children who had surgery out of nineteen children who were staged. In this small population, anatomically based supraglottoplasty has been successful. A careful review of our series shows the importance of a full airway assessment prior to surgical correction and displays the benefit of basing the surgical approach upon the responsible anatomy. We feel that our increasing use of pre-operative staging forms facilitates an anatomic and outcomes-based approach that optimizes the management of this common pediatric airway problem.

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SCULPTING ENDOBRONCHIAL STENTS WITH ND:YAG LASER.
James S. McCaughan, Jr. Grant Medical Center and Laser Medical Research Foundation, Columbus, Ohio.

Purpose: Occasionally stents will cross the opening to bronchi that are not obstructed. This technique modifies the stent to create windows in the stent, remove excessive stent material, or help remove stents that are no longer functioning properly.

Methods: Following placement of endobronchial stents, the stent is modified using a bare tip fiber and a Nd:YAG laser at 50 watts.

Results: 50 watts delivered from the straight tip fiber and a Nd:YAG laser disintegrates and vaporizes the wire mesh of the stent and permits sculpting the stent to suit needs.

Conclusion: 50 watts of Nd:YAG laser can be used safely to sculpt the wire mesh of endobronchial stents through an endotracheal tube using general anesthesia when the FIO_2 is kept below 40%.

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COCHLEAR DYSFUNCTION AND LOW-LEVEL-LASERTHERAPY: DOSIMETRIC ASSESSMENT OF LASER-LIGHT-DISTRIBUTION IN THE HUMAN PETROUS BONE
[1]St. Tauber, [2]W. Beyer, [1]K. Schorn, [1]G. Grevers, [2]R. Baumgartner
[1]Dept. of Otolaryngology, Head and Neck Surgery and [2]Laser-Research-Laboratory, University of Munich, FRG
The clinical low-level-lasertherapy (LLLT) of the human labyrinth with in-vitro obtained light-dosimetrical parameters in case of cochlear dysfunction requires an experimental light-dosimetric analysis.
Methods:
Human anatomic formalin-conserved specimen of petrous bones (n=20) were investigated for proper anatomical structures by macro- and microscopic analysis and a high-resolution CT-scan (1mm tomography). The bony cochlea was opened retrocochlearly along the internal auditory meatus and the membranous labyrinth of the cochlea was removed. Irradiations of the mastoid and the tympanic membrane, respectively, were performed with HeNe and diode lasers of different

wavelengths (λ=612, 635, 690, 780, 830nm) with different laser fibers (microlens emitter, isotropical emitter). The laser light, transmitted across the promontory bone and emitted within the cochlea, was quantified by means of (i) a calibrated fiber detector within the cochlea and (ii) by a computer-controlled CCD-camera, respectively. The spacial distribution of light was analyzed according to the tonotopic organization of the cochlear windings and the type and position of the radiator. The ratio between the space irradiance, assuming an intact cochlea, and the measured irradiance was obtained by Monte Carlo calculations, enabeling a comparison with the results of light-dosimetrical cell experiments.

Results:

The transmission of light across the tympanic cavity and the promontory depends strongly on the wavelength and the type and position of the radiator. The cochlear light distribution is markedly inhomogenous, demonstrating the impact of pre-clinical light dosimetric investigations for effective individual laser irradiation.

Conclusions:

Dosimetric evaluations are mandatory for defined energy doses of laser-irradiation within the human cochlea, in order to transfer in-vitro analyzed irradiation parameters of LLLT to the human auditory hair cell.

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LASER ASSISTED MYRINGOTOMY (OTOLAM)

Yosef P. Krespi, MD
New York, NY

Laser assisted myringotomy (OtoLAM) was performed on 200 ears to aerate the middle ear cavity. 70% of our patients were represented by children from ages 1 to 12 years of age. Otitis Media in children is a major health care problem in the United States accounting for approximately 25 Million patient visits each year. It is estimated that over 1 million Myringotomies and ventilation tubes were performed by Otolaryngologists each year. The overall cost in treating otitis media by the healthcare industry was estimated to be 5 Billion dollars in 1994.

Laser assisted myringotomy (OtoLAM) was performed in children and adults (ages ranging 1-72) under topical anesthesia without a need for a pressure equalizing tube. We will present our experience in treating acute otitis media and serous otitis media with effusion using an OtoLAM scanning device attached to a CO2 laser. A 2.2 - 2.6mm circular opening was performed using 15-20 watts of energy for laser tympanolysis. The patency time was directly correlated to the size of the myringotomy opening. Closure time varied from 12 to 27 days with a mean of 19 days. Over 97% of the myringotomies healed without noticeable scarring. No persistent perforation was noted in our series. OtoLAM can be performed in an office setting under video control without the need of general anesthesia and insertion of ventilation tubes. OtoLAM appears to be a safe, easy and cost effective procedure.

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REPORT ON MORE THAN EIGHT YEARS OF LOW LEVEL LASER THERAPY OF CHRONIC INNER EAR DISEASES

Lutz Wilden, Sabine Schübel, Bad Füssing, Germany

The paper investigates the effects of low level laser light on chronic inner ear diseases. The criteria of the therapeutic success are changes of the air and bone conduction in the audiometries made immediately before and after the therapy. Further criteria are the changes of the symptoms: sensation of pressure in the ear, changes of the dysacusia, amelioration of the vertigo, changes in the intensity and the character of the tinnitus. Since 1990 more than 800 patients suffering from inner ear diseases are treated with low level laser light and the therapy results are examined with retrospective therapy studies. The main reason for doing this is the fact that although diseases of the inner ear are rapidly increasing all over the world, conventional treatment methods have proved to be highly therapy-resistent and offer patients little prospects of being cured. More than 90% of the persons, who received an adequate low level laser light treatment in my office, showed a high average age and were suffering from serious and complex inner ear diseases. The age of more than 70% of the patients was over 50 years. In the preliminary stages of the therapy, they were all examined by means of a MRT scanner to rule out any tumourous diseases of the central nervous system. The therapy itself was carried out under standardized conditions as far as the positioning of the patients and the application and dosage of low level laser light were concerned. It can be shown that all clinically relevant symptoms of inner ear diseases regress within a biologically explicable span of time if treated with sufficiently high dosages of low level laser light (corresponding figures and tables will be presented at the congress). As the effect of the therapy is especially positive if it is combined with an extensive radiation treatment of the periarticular body areas via mastoid, meatus and middle ear, I will point out the dosages and means of application of low level laser light that lead to the best possible results at present. Furthermore, I will discuss the prognostic statements to be made on the basis of the original clinical findings such as age, anamnesis and audiometry, describe how low level laser light can be utilized for prophylactic measures against inner ear diseases and present a mobile treatment system, which enables patients to carry out a long-term therapy at home. It is urgently necessary that the therapy with low level laser light under standardized conditions is made accessible to the general public; is produces no side-effects in the sense of a lasting deterioration in the patient's condition or any other intolerability.

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PHOTOFRIN® - PDT IN ONCOLOGICAL APPLICATIONS: AN OVERVIEW

Boniface G. QLT PhotoTherapeutics. Vancouver, B.C. Canada

PHOTOFRIN® (porfimer sodium) is the only light-activated drug approved anywhere in the world. PHOTOFRIN® has been studied in more than 3000 patients, with at least 10 different tumor types showing evidence of clinical activity.

Multicenter randomized trials have been conducted with PDT using PHOTOFRIN® in patients with obstructive esophageal cancer and obstructive endobronchial lung cancer versus thermal ablation using Nd:YAG laser treatment. At one month after treatment, patients treated with PHOTOFRIN® have statistically significant higher response rate than those treated with Nd:YAG (32% versus 20% in esophageal cancer, and 55 % versus 29% in endobronchial lung cancer respectively : $p<0.05$). Patients with obstructive esophageal cancer had less perforation with PHOTOFRIN® (1%) than with Nd:YAG thermal ablation (7%) [$p<0.05$]. Open non-comparative trials have also been conducted in early superficial endobronchial lung cancer patients who were not eligible for surgery. PDT treatment with PHOTOFRIN® resulted in a histological Complete Response in 79% of patients (95% CI of 71 to 87%) with median Disease-Specific Survival of 5.7 years and median survival of 3.5 years. In those patients, PHOTOFRIN® PDT offers the advantage of being tissue-sparing, as it preserves the lung function, particularly in patients with prior surgery or radiotherapy or patients with multiple primary tumors. Other interesting phase II trial data with PHOTOFRIN® show approximately 80% Complete Response Rate in early head and neck tumors (mainly Tis or T1 oral cavity and laryngeal tumors), and 93% response rate in patients with high grade dysplasia of Barrett's esophagus.

The difference in potency, activation wavelength, and light dosimetry between different photosensitizers and for different tumor types makes the prospective study and establishment of these parameters for each tumor type essential, prior to recommending their use in the individual indications. Clinical development of photosensitizers must include controlled. randomized multicenter trials.

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CLINICAL PHOTODYNAMIC THERAPY (PDT) USING TOPICAL LEVULAN® (AMINOLEVULINIC ACID HCL, ALA).
S L Marcus[1], D G Shulman[1], , R Carroll[1], S Lundahl[1], R Kozodoy-Pins[1] and A L Golub[2], DUSA Pharmaceuticals, Inc.
[1]Valhalla, NY, [2]Guidelines, Inc., Miramar FL.

Topical cutaneous or mucosal application of ALA can result in the accumulation of porphyrin precursors, particularly the endogenous photosensitizer protoporphyrin IX (PpIX). If sufficient intracellular PpIX concentrations accumulate, light exposure to wavelengths in the range of 400-650 nm, at appropriate energies, can either produce a photodynamic effect or can be used for fluorescence detection (photodetection, PD) of malignancies or dysplasias.

DUSA is developing Levulan-based systems using specific topical formulations and light sources for PDT and for PD. In 1998, DUSA filed an application for marketing approval in the USA with the FDA for the use of Levulan and blue light in the treatment of multiple actinic keratoses (AKs) of the face and scalp. The pivotal clinical trials for this indication accrued a total of 243 patients, utilized overnight application of a 20% Levulan topical solution in a unique dosage form and a portable, cost-efficient blue light source, which can treat the entire face or scalp at once. Approximately 90% of AK lesions completely responded to topical Levulan® PDT treatment. Clinical trials are actively under way testing Levulan® PDT for permanent hair removal, for treatment of acne, and for endometrial ablation. DUSA is also exploring the use of topical Levulan PDT and PD for urological and for gynecological indications.

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PDT for the Treatment of Brain Tumors

Paul Muller, St. Michael's Hospital, Michael Hitchcock, HealthONE Swedish Medical Center, Robert Selker, West Penn Hospital, Robert Fenstermaker, Roswell Park Cancer Center, Judith Abrams, Henry Ford Hospital, Brian Wilson & Lothar Lilge, Princess Margaret Hospital, Qun Chen & Fred W. Hetzel, HealthONE.

We are currently conducting 2 four center, prospective randomized clinical trials to investigate the utility of adding photodynamic therapy (PDT) to best conventional therapy in the treatment of grade III and IV supratentoral astrocytomas and glioblastoma multiforme. For the purposes of this investigation, PDT employs the photosensitizere porfimer sodium (Photofrin™, QLT Phototherapeutics, Vancouver BC) activated by 632 nm light. One protocol is for the treatment of newly diagnosed disease and the second is for recurrent disease. Complete details of the patient inclusion and exclusion criteria for each of the protocols will be presented as will the complete details of the treatment regimens.

Basically, for newly diagnosed lesions, PDT is applied intraoperatively at the time of surgery. These procedures are followed by conventional radiation therapy and chemotherapy. Recurrent lesions are defined for the purposes of this investigation as those which have failed an initial surgery and radiation therapy. Patients with recurrent lesions are randomized between high dose versus low dose PDT in conjunction with reoperation. Patient accrual into these protocols commenced in May 1998. Preliminary data and analysis of results for these early patients will be presented. Results of the single site, pilot study conducted by Muller et al. which led to the current investigations will also be presented as will details of associated photo-physics investigations conducted in parallel with the clinical applications.

This work supported in part by grant number CA 43892 from the National Cancer Institute. The contents of this presentation are solely the responsibility of the authors and do not necessarily represent the official views of the National Cancer Institute.

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TUMOR BLOOD FLOW CHANGES FOLLOWING PROTOPORPHYRIN IX-BASED PHOTODYNAMIC THERAPY IN MICE AND HUMANS

Mark Herman, David Fromm, and David Kessel
Wayne State University, Department of Surgery, Detroit, MI

The effects of aminolevulinic acid (ALA)-based photodynamic therapy (PDT) on tumor blood flow are controversial. This study examines the effects of ALA and Photofrin-based PDT on blood flow of colon-26 tumors implanted in mice, as well as the effects of ALA-based PDT on blood flow of human colorectal carcinomas and a carcinoid tumor in situ. Tumors were implanted in both flanks of mice. One tumor of each animal served as a control. Blood flow was measured using a laser doppler method. Tumor blood flow in mice not receiving a photosensitizer but treated with three different light doses (50, 100, and 150 J/cm^2) did not differ significantly from blood flow in the untreated opposite flank tumor. PDT after ALA administration using the three light doses did not significantly effect blood flow. In contrast, PDT after Photofrin administration caused a significant decrease in blood flow with each light dose. In contrast to mice, six patients who received ALA prior to surgery all showed a decrease in tumor blood flow after PDT using 100 J/cm^2. It appears that the effect of ALA-based PDT on blood flow is dependent on the model studied, and this may be a reflection of differences between various tumors or tissues. Furthermore, the observed decrease in blood flow in human tumors in situ and the lack of an effect in mice following ALA-based PDT suggests that light dosing studies in animals treated with ALA may not be applicable to humans.

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Photodynamic Therapy with Purlytin for Recurrent Breast Carcinoma,

Mang TS, Moskowitz R, Cooper R, Hewson G, Snider WL and Allison R.

Introduction: Recurrence of breast cancer following surgery, radiation and chemo\hormonal therapy is a therapeutic dilemma. Photodynamic Therapy (PDT) may offer an option.

Results: Eleven women, with biopsy proven recurrence underwent a single outpatient PDT session using the new photosensitizer, Purlytin (SnET2; Miravant Pharmaceuticals). A total of 130 lesions ranging from 0.3-3.9 cm were treated followed 24 hours post injection of 1.2mg\kg of Purlytin by laser treatment at 660 nm ± 3nm. The total light dose used was 200 J\cm^2 at a dose rate of 150mW\cm^2. With follow-up of 3- 12 months the complete response (CR) was 91% with 9% partial response rates. No new lesions reappeared within a CR field.

Discussion: PDT with Purlytin offers excellent response rates and palliative effects for chest wall recurrences, especially for small lesions. PDT should be considered earlier in the salvage course as morbidity is low and response gratifying.

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Purlytin (SnET2) induced Photodynamic Therapy (PDT) for Kaposi's Sarcoma (KS).
Mang TS, Snider WL, Hewson G, and Allison R.
PDT Center Buffalo General Hospital.

Introduction: Currently available therapies for KS all too often are clinically and cosmetically unsuccessful. We examined the role of PDT in the treatment of patients presenting with this disease.

Results: A total of 116 biopsy proven KS lesions arising on eight HIV patients, underwent one PDT session. The drug Purlytin (SnET2; Miravant Pharmaceuticals) was administered at 1.2mg\kg and activated twenty-four hours later, by 660nm ± 3nm of light delivered via fiberoptic from a diode laser system. The total light dose was 300J/cm^2 delivered at a power density of 150 mW/cm^2. With minimum follow-up of 6 months, complete response (CR) rates, defined as no clinical lesion nor residual pigmentation, were seen in 81% of lesions (94 of 116), 19% had a partial response. Morbidity was limited to mild photosensitivity.

Conclusion: PDT with Purlytin is a well tolerated outpatient procedure that offers excellent clinical and cosmetic response rates.

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PHOTODYNAMIC THERAPY (PDT) FOR BARRETT'S ESOPHAGUS: EFFECT OF STEROID THERAPY ON STRICTURE FORMATION
Masoud Panjehpour, Bergein F. Overholt, John M. Haydek
Laser Center, Thompson Cancer Survival Center, Knoxville, TN.

Purpose: The goal of this study was to investigate whether the use of oral steroid would improve the incidence of stricture formation after balloon PDT in Barrett's esophagus patients.
Methods: 60 patients were treated with photodynamic therapy. Photofrin (2 mg/kg) was injected intravenously. 630 nm laser light was delivered two days later through a 25 mm balloon catheter. A KTP/Dye laser was used as the light source. Patients were randomized (50/50) to either receive PDT treatment alone or PDT treatment followed by steroid therapy. Prednisone was administered orally at a dose of 60 mg x 2 days, 50 mg x 2 days, ..., 10 mg x 2 days starting after the laser treatment. 30 patients received PDT treatment alone. 30 patient received PDT and steroid therapy. Light dose of 200 J/cm or 175 J/cm was delivered.
Results: In the group receiving PDT alone, 30% developed stricture (9/30). When excluding patients that received two or more treatments and those with preexisting stricture, 22% developed stricture. 50% of patients (3/6) that were retreated developed stricture, all due to treatment overlap. In the group that received PDT and steroid, 36% developed stricture (11/30). Excluding patients with multiple treatments and preexisting stricture, 30% developed stricture (7/23). 50% of patients that cture (3/6), with 2/3
due to treatment overlap.
Conclusion: Oral administration of steroid after PDT treatment of Barrett's esophagus did not improve the incidence of stricture formation.

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ATHEROMATOUS PLAQUE REDUCTION WITH ANTRIN™ PHOTOANGIOPLASTY. K. W. Woodburn, Pharmacyclics, Inc.

The selectivity of ANTRIN™ Injection (a lutetium texaphyrin sensitizer for photoangioplasty) with subsequent photoillumination was evaluated preclinically in two experimental rabbit atheromatous plaque models; a hypercholesterolemic diet model and a balloon injury model of restenosis.
Animals were given 10 umol Antrin/kg intravenously. At 24, 48 and 72 hours post injection, accumulation of Antrin within the plaque and adjacent normal aortic wall, as assessed by fluorescence spectral bioimaging and chemical extraction studies were performed. Intra-arterial illumination was performed on another subset of animals with non-thermal 732 nm light using a 0.9 mm optical fiber with a 3 cm cylindrical diffuser 24 hours post sensitizer injection. Two weeks following treatment the vessels were harvested and histology was performed.
Fluorescence characterization of the two experimentally induced lesions revealed a significant difference in sensitizer accumulation within plaque as compared to sensitizer detected in the surrounding normal aortic wall and adventitia. Administration of intra-arterial light resulted in selective plaque destruction without evidence of endothelial damage and intimal hyperplasia.
Antrin is a water-soluble, phototherapeutic agent that is rapidly cleared from the plasma, accumulates in plaque and is activated by blood/tissue penetrating non-thermal light causing select damage to the target lesion. Clinical trials are currently ongoing in patients with peripheral arterial disease to assess the safety and efficacy of this new investigational modality.

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PHOTODYNAMIC THERAPY OF PRIMARY SQUAMOUS CELL CANCERS OF THE ORAL CAVITY USING MTHPC
A.Kuebler MD DMD, C.Staff MD, T.Haase PhD, J.Mühling MD DMD
Dept of Oral and Maxillofacial Surgery, University of Heidelberg, INF 400, 69120 Heidelberg Germany
German Cancer Research Center Heidelberg Germany
Seventeen patients with a primary squamous cell cancer (SCC) of the oral cavity $T_{1\text{-}2}N_0M_0$ (13 patients T_1; 4 patients T_2) were treated with mTHPC (Foscan®) mediated photodynamic therapy (PDT). Prior to PDT all patients underwent a detailed examination including

ultrasound, CT scan and scintigraphy in order exclude local or distant metastasis. All patients received 0.15mg/kg Foscan intravenously 96 hours prior to PDT. Light treatment was conducted using an argon-dye laser at 652nm, 100mW/cm^2 and 20J/cm^2 and superficial microlens applicator.
Fifteen patients showed a complete response with a mean follow up of 12.7 months. One patients (T_1) showed a partial response with a reduction of tumor size by more than 50% and one patient (T_2) showed tumor recurrence 6 months after PDT.
In two patients, both with complete local tumor response, cervical lymph node metastasis occured 2 and 5 months respectively after PDT. These patients underwent successful neck dissection thereafter. As a side effect short lasting systemic skin photosensitivity for 2 weeks occured with two patients suffering from mild sunburn. All patients reported about severe pain for up to three weeks which was controled by oral or transderma. opiate analgesic support. Functional as well as cosmetical results were excellent and superior to conventional therapy.
On this limited number of patients, PDT of SCC of the oral cavity seems to be an alternative to conventional therapy methods. The risk of regional lymph node metastasis forces a long term follow up or a prophylactic regional lymph node dissection immediately after PDT.

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SUBCELLULAR LOCALIZATION AND PHOTODYNAMIC ACTIVITY WITH ALKYL ETHER DERIVATIVES OF PYROPHEOPHORBIDE-a. Ian J. MacDonald[1], David A. Bellnier[1], Janet Morgan[2], Thomas J. Dougherty[1]. Photodynamic Therapy Center[1] and Department of Dermatology[2], Roswell Park Cancer Institute, Buffalo NY.
For this work we examined whether differential subcellular localization patterns exhibited by members of a congeneric series of pyropheophorbide-a (pp-a) ethers could account for their differing photodynamic activities exhibited *in vivo*. Drug localization was examined in cultured FaDu, RIF, and PDT-resistant RIF cells using fluorescence microscopy. *In vitro* survivability was quantified with MTT and clonogenic assays, and drug uptake was measured using fluorometry. Both fluorescence and UV-visible spectroscopy were used to study aggregation properties of the compounds.
Hydrophobicity, as indicated by the logarithm of the octanol-water partition coefficient (Log *P*), appeared to determine the organelle into which the compound localized, with the least hydrophobic compounds localizing more mitochondrially. It was found that several of the pp-a ethers that localized to the mitochondria exhibited greater photodynamic activity *in vivo* than congeners that localized in the lysosomes. However, despite exhibiting mitochondrial localization patterns, the highest cellular uptake values and optimal photodynamic activity *in vitro* some of the least hydrophobic members exhibited decreased *in vivo* PDT activity. This was likely due to rapid serum clearance. These results reinforce the hypothesis that mitochondria are a sensitive PDT target.

PLENARY SESSION

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LASER IN HEART TRANSPLANT RECIPIENTS - A NEW TREATMENT MODALITY

On Topaz, M.D., FACC, Med Coll of VA and McGuire VAMC, Richmond, VA USA

Accelerated allograft coronary disease significantly reduces survival of heart transplant recipients. The prevalence of allograft disease is as high as 18% by 1 year and 50% by 5 years following heart transplant. Sudden death and heart failure are the two most common clinical presentations of this devastating disease. Treatment is challenging: repeat transplant is a rare option and bypass surgery carries a high mortality. A number of percutaneous revascularization techniques, mainly balloon angioplasty, have been used as a palliative treatment with mixed results. Recently, we began using lasers in these patients for the purpose of plaque removal and for TMR (transmyocardial revascularization). The "cold", pulsed-wave excimer and holmium:YAG laser are used. Early results are promising, suggesting a potential role for laser as a revascularization option in selected heart transplant recipients. This presentation will provide the rational for laser in this setting, the clinical background and the early results with this new approach.

PODIATRY

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EVALUATION FO THE HOLMIUM YAG ENDOSCOPIC RELEASE OF TARSAL TUNNEL
N. David Wright, D.P.M. Therapeutic Laser Corporation, Strongsville, OH 44136
The purpose of the study is to evaluate the efficacy and safety of an endoscopic approach for the release of Tarsal Tunnel on a clinical basis.
The methods used were a comparison between the conventional open release of the Tarsal Tunnel with a one-year follow up. The parameters to evaluate the morbidity of the surgical procedure included 1. Lengths of time in operating room 2. Post op pain on a numerical qualitative checklist 3. Time to return to normal activity 4. Recurrence of preoperative symptoms 5. Post operative untoward occurrences (e.g. Infection, reflex sympathetic dystrophy)
The method of laser surgery included the use of a holmium Yag endoscopic approach to an area under the retinaculum. The retinaculum was released until a digital plethysmograph on the hallux demonstrated an increase in circulation (since the vessel runs with the nerve). At that point the surgery was finished. This was in comparison to the open technique.
Results-Compared to open techniques the endoscopic release resulted in almost immediate ambulation (after 48 hours) vs. 14-15 days with ambulatory aid in the open technique. The laser technique demonstrated
A 73% greater patient satisfaction rate based on the parameters of pain diminution, lack of untoward surgical effects and one-year follow up.
The conclusion demonstrates that endoscopic release of tarsal tunnel can be effective and should be further evaluated.